UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 03/28/2016

SUBJECT: **Aldicarb.** Acute Aggregate Dietary (Food and Drinking Water) Exposure and
Risk Assessments for Registration Review Risk Assessment.
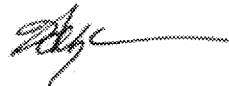
PC Code: 098301	**DP Barcode:** D430197
Decision No.: 498310	**Registration No.:** 87895-1
Petition No.: NA	**Regulatory Action:** Registration Review
Risk Assessment Type: Dietary	**Case No.:** 0140
TXR No.: NA	**CAS No.:** 116-06-3
MRID No.: NA	**40 CFR:** §180.269
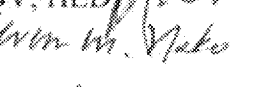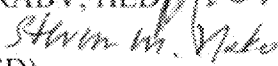
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Executive Summary

Acute aggregate dietary (food only, food and drinking water, and drinking water only) exposure
and risk assessments were conducted using the Dietary Exposure Evaluation Model software
with the Food Commodity Intake Database (DEEM-FCID) Version 3.16. This software uses
2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's)

National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The analyses were conducted in support of the registration review risk draft risk assessment (DRA). This memorandum was reviewed by two peer reviewers of the DESAC (and the entire DESAC on 12/10/2015), per DESAC SOP 2012.1.

Acute dietary exposure assessments incorporated USDA Pesticide Data Program (PDP) monitoring data for aldicarb and its metabolites aldicarb sulfoxide and aldicarb sulfone, anticipated residues, field trial data, tolerances, empirical processing factors, default DEEM processing factors, and percent crop treated (CT) estimates. Aldicarb metabolites were assumed to have similar toxicity to the parent. The Environmental Fate and Effects Division (EFED) provided daily time series outputs for the scenario that provided the highest and lowest estimated drinking water concentrations (EDWCs). The highest EDWC was for surface water in Minnesota (MN sugar beets PRZM scenario) after application of the rate used for sugar beets (named thereafter MN Sugar Beets). The scenario that provided the lowest EDWC was surface water in California (CA cotton PRZM scenario) after application of the rate used for cotton (named thereafter CA Cotton).

Acute assessments were conducted for food only, drinking water only, and food and drinking water. Although the 2010 mitigation agreement indicated that tolerances for pecan, sorghum, sugarcane, citrus, and potato were going to be revoked these commodities still have tolerances for aldicarb in the 40 CFR. Therefore, these commodities were considered in the dietary assessment assuming that residues of aldicarb may be present in imported commodities. As such, these commodities were included in the dietary assessment considering the percent of imports for those for which data was available and assuming that 100% of the imported crop is treated. Coffee was included in the 2010 dietary assessment in support of use on the imported commodity. Commodities with registered uses in the U.S.A. were included with their corresponding %CT. Sugar beet and sugarcane were excluded from the assessments, since aldicarb residues would not be expected in the processed commodities as consumed.

This assessment incorporated an estimated half-life for red blood cell (RBC) cholinesterase (ChE) inhibition of two hours which is based on data of aldicarb from rats and human subjects. HED also refined the acute dietary risk from food and drinking water by incorporating the time and amounts consumed for each eating occasion from the USDA NHANES/WWEIA food diaries to estimate exposures and risks on each eating occasion throughout the day and factoring in the ChEI half-life related to aldicarb exposure. Refer to C. Olinger memo (D299883, 08/16/2010) for additional information on the eating occasion analysis.

A preliminary screening showed that the acute dietary exposure estimates from food alone was above HED's level of concern (i.e. >100 % of the aPAD) at the 99.9[th] percentile of exposure. The commodity with highest contribution to the risk was potato tubers which do not have domestic uses currently registered for aldicarb. PDP data for potato (2006-2009) were modified to eliminate contribution from domestic samples. An acute dietary assessment using only detects from samples of imported potatoes results in risks below the level of concern (i.e. <100 % of the aPAD) at the 99.9[th] percentile of exposure. Aldicarb food only dietary exposure estimate is 65% of the aPAD for children 1-2 years old, the most highly exposed population subgroup, and 25% of the aPAD for the general population. However, the commodity specific analysis results in

exposure estimates above 100% of the aPAD following consumption of an estimated single serving of sweet potato or potatoes.

Exposures are above the level of concern (LOC) for drinking water only. Dietary exposure estimates ranged from 1,400% to 2,900%, and 150% to 340% of the aPAD at the 99.9[th] percentile of exposure for the general population and most population subgroups using the scenarios that resulted in the highest EDWC (MN sugar beets) and lowest EDWC (CA Cotton), respectively. Similarly, for food and drinking water, the dietary exposure is above HED's LOC using drinking water scenarios that provided the highest EDWC (MN sugar beets).

A chronic assessment was not conducted because the toxicity database for aldicarb indicates that cholinesterase inhibition (ChEI) is the most sensitive effect found, the magnitude of ChEI does not increase with continued exposure, and that ChEI is generally reversible within 24 hours at the levels relevant to the dietary risk assessment. The longer-term exposures could be considered as a series of acute exposures, with regard to ChEI. All other effects noted in the sub-chronic and chronic toxicity studies were observed at higher doses. Aldicarb is classified as not likely to be carcinogenic to humans; therefore a cancer dietary assessment was not conducted.

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose that HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population-adjusted dose (PAD). The PAD is equivalent to the point of departure (POD, NOAEL, LOAEL, e.g.) divided by the required uncertainty or safety factors.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. References that discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 21-JUN-2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf; or see SOP 99.6 (20-AUG-1999).

The most recent dietary risk assessment for aldicarb was conducted by C. Olinger (08/16/2010, D299883).

II. Residue Information

Residues of Concern

The residues of concern for tolerance enforcement and risk assessment are the combined residues of aldicarb and its two cholinesterase-inhibiting metabolites aldicarb sulfoxide [2-methyl-2-(methylsulfinyl)propionaldehyde O-(methyl carbamoyl) oxime] and aldicarb sulfone [2-methyl-2-(methylsulfonyl)propionaldehyde O-(methyl carbamoyl) oxime]. In field trials, parent aldicarb is typically at or just above the limit of detection (LOD); however, residues of aldicarb sulfoxide

and/or aldicarb sulfone are detected more often and at higher levels than that of aldicarb. Aldicarb sulfoxide residues are found more frequently than the sulfone, and tend to be higher than sulfone residues when both are present. In monitoring data, parent aldicarb is rarely detected. Aldicarb sulfoxide is considered to be as potent as the parent in terms of toxicity, while the sulfone is less potent. For risk assessment, the metabolites are assumed to have toxicity equivalent to parent compound aldicarb.

Tolerances

Tolerances are established in the 40 CFR § 180.269 for the use of aldicarb on bean, sugar beet, coffee, cotton, grapefruit, lemon, lime, orange, peanut, pecan, potato, sorghum, soybean, sugarcane and sweet potato. These tolerances are based on measurement of combined residues of aldicarb and its cholinesterase-inhibiting metabolites aldicarb sulfoxide [2-methyl-2-(methylsulfinyl)propionaldehyde O-(methyl carbamoyl) oxime] and aldicarb sulfone [2-methyl-2-(methylsulfonyl)propionaldehyde O-(methyl carbamoyl) oxime] and range from 0.02 to 1 ppm. The tolerances for dry bean, sugar beet, cotton, peanut, soybean and sweet potato are based on domestic uses of aldicarb. Coffee was included in the 2010 dietary assessment in support of use on the imported commodity. Although tolerances for potato, citrus, coffee, pecan, sorghum and sugar cane are established in the CFR, there are no registered uses in the U.S.A. As tolerances for these commodities are in the CFR at this time, these commodities were considered in the dietary assessment assuming that residues of aldicarb may be present in imported commodities. Although livestock feedstuffs are associated with uses of aldicarb, tolerances are not established for livestock commodities because transfer of residues to livestock commodities is not expected (i.e., a 40 CFR §180.6(a)(3) situation applies) (W. Donovan, D425180, *In Progress*).

Anticipated Residues

USDA PDP monitoring data for potato, sweet potato, and orange (translated to other citrus commodities) were incorporated in the dietary assessment. The PDP was specifically designed for risk assessment; analysts prepare samples in a manner similar to typical consumer practices, such as washing, coring, and peeling. In years 2006 to 2012, USDA PDP analyzed several commodities for residues of aldicarb and its metabolites separately. PDP monitoring data were used for residues of aldicarb and its metabolites in/on potato, sweet potato, and citrus (orange, lemon, lime and grapefruit). Field trial data provided in the previous dietary assessment (C. Olinger, D299883, 08/16/2010) were used for soybean, dry beans, pecan, cottonseed, coffee and peanut. Tolerance-level residue was used for sorghum. Sugar beet and sugarcane were excluded from the assessments, since aldicarb residues would not be expected in the processed commodities as consumed. Attachment A.1.2 and A.1.3 summarizes the residue inputs (anticipated residues, processing factors, PCT, etc.) and all of the residue distribution files (RDFs), respectively, used for the acute assessment.

Residues of parent aldicarb, aldicarb sulfone, and aldicarb sulfoxide were combined using a Statistical Analysis System (SAS) program that matches residues from the same samples using the PDP sample IDs. The SAS program directly created the RDFs for use in the acute analysis. In some cases, residues of either aldicarb or its metabolites may have not been detected or the samples may not have been analyzed for all residues. The set of rules outlined in Table 1 were

used to combine the residues for each sample. The total residue was calculated as aldicarb using the following formula, which accounts for the difference in molecular weights of the parent and two metabolites:

Total residue (as aldicarb) = aldicarb + (aldicarb sulfone x 0.86) + (aldicarb sulfoxide x 0.92)

In order to incorporate non-detectable residues into the exposure assessment, HED used the current policy [refer to ChemSAC memo dated 5/19/98 and HED SOP 99.6] of assigning residue values of ½ LOD to these samples. If the residues were determined as the sulfone, then the ½ LOD for the total residue determined as the sulfone was used in the analysis. When the parent and metabolites were determined individually, using a ½ LOD of 0.005 ppm (i.e., LOD = 0.01 ppm) for aldicarb and each of its metabolites, for example, the combined ½ LOD is as follows:

Total ½ LOD residue (ppm) = 0.005 + (0.005 x 0.86) + (0.005 x 0.92) = 0.0139 ppm

In the case of field trial data, which is reported on an aldicarb sulfone basis, the conversion to the aldicarb basis is done using the following formula, which accounts for the differences in molecular weights:

Aldicarb residues = aldicarb sulfone residues (ppm) x 0.86

Table 1. Method for Combining Residues of Aldicarb and it Sulfone and Sulfoxide Metabolites from the Same PDP Sample.		
Aldicarb	Metabolite	Data Treatment[1,2]
detect	detect	Aldicarb detect + Metabolite detect
detect	non-detect	Aldicarb detect + ½ LOD for Metabolite for that sample
non-detect	detect	½ LOD for Aldicarb for that sample + Metabolite detect
non-detect	non-detect	Highest ½ LOD for Aldicarb + ½ LOD for Metabolite

[1] The highest limit of detection (LOD) for aldicarb and its metabolites was used to estimate the LOD to be included in the RDF file or used in point estimate calculations. When aldicarb or its metabolites were not detected, the ½LOD of that sample was used and added to the concentration of the analyte that was detected.

Processing Factors

Processing factors (PFs) for aldicarb in cooked potato food forms (0.62 for fried; 0.5 for boiled), dry beans (0.05 for baked, boiled, fried, canned:cooked, canned:boiled, cooked:no food form specified), soybean oil (0.3), peanut oil (0.18), and cottonseed oil (0.1), sugarcane, and sugar beet have been generated in processing/cooking studies submitted in support of reregistration. The studies were considered to be acceptable and appropriate for use in risk assessment and tolerance reassessment. The processing/cooking studies indicate a general reduction of residues; since residues are systemic, the reduction in residues is not related to removal of certain inedible commodity fractions, e.g., peel. Aldicarb processing factors to specific food forms in DEEM is described in Table 2. Moreover, DEEM default processing factors of 6.5 for dry potato and 1 for the remaining processed commodities were used. Processing factors for citrus juice were not needed as PDP data for orange juice was available.

Table 2. Summary of Aldicarb Processing Factors (PFs) Used in the Dietary Exposure Analyses

Commodity/Processed Food Form	PF[1]	Application of PF to Relevant Food Forms in DEEM
Potato, dry	6.5	Potato, dry; Potato, flour
Potatoes/fried	0.62	Potato and Sweet potato:Fried
Potatoes/boiled, cooked	0.5	Potato and Sweet potato - boiled, canned:cooked, canned:boiled
Beans, dry	0.05	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NFS
Peanut/oil	0.18	Peanut/Oil
Soybean/oil	0.3	Soybean/Oil
Cottonseed/oil	0.1	Cottonseed/Oil
Sugarcane/sugar beet	NA	NA

[1]Processing factors were entered into the DEEM software as Adjustment Factor 1.

Residues in Fish

The USDA PDP monitored pesticide residues in catfish in 2008, 2009, and 2010. Over this 3-year period, PDP analyzed 1479 samples of catfish for residues of aldicarb and aldicarb sulfone, and 552 samples for residues of aldicarb sulfoxide. None of the samples contained detectable residues. Moreover, PDP monitored pesticide residues in salmon in 2013. Over this 1-year period, PDP analyzed 88 and 29 samples of salmon for residues of aldicarb sulfone and aldicarb sulfoxide, respectively. None of the samples contained detectable residues. As a result, residues in fish were not included in the assessment.

III. Percent Crop Treated Information

The Biological Economic Analysis Division (BEAD) provided percent of crop treated estimates for the years 2004 to 2012. The following maximum percent crop treated estimates (Updated Screening Level Usage Analysis Report for Aldicarb, PC Code 098301; 12/18/2014) were used in the acute dietary risk assessment for the following crops that are currently registered for aldicarb: cotton: 35%; dry beans: 2.5%; peanuts: 45%; soybeans: 2.5%; and sugar beets: 10%. 100% of crop treated was assumed for sweet potato. Percent of crop treated estimates were provided for grapefruit, oranges, lemon, pecans, potato, sorghum, and sugarcane; however, these were not used as these crops do not have uses registered in the U.S.A. BEAD provided information on the percent of imported commodities for which data was available from 2009-2013 (e-mail from Donald Atwood; 11/25/2015). The percent of imports were included for the following crops: grapefruit: 2%; lemons: 10%; orange: 8%; pecans: 58%; fresh potato: 8%; frozen potato: 21%; and 100% was assumed for limes and coffee.

IV. Drinking Water Data

The drinking water residues used in the dietary risk assessment were provided by the EFED in the following memorandum: "**Aldicarb:** Drinking Water Exposure Assessment for Preliminary Risk Assessment" (D427697, Edmund Wong, 06/17/2015) and incorporated directly into this dietary assessment. Water residues were incorporated in the DEEM-FCID into the food categories "water, direct, all sources" and "water, indirect, all sources."

Tier II surface water EDWCs were estimated with the Surface Water Concentration Calculator (SWCC). The Pesticide Root Zone Model-Groundwater (PRZM-GW) was used to estimate groundwater EDWCs at a pH of 6. TTR degradation varies across pH; therefore, slight acidic conditions yielded the highest concentration of aldicarb TTR in groundwater. Available monitoring data were also evaluated, however, the monitoring studies were non-targeted. Thus, these data are not expected to provide an upper bound estimate of the potential exposure to aldicarb TTR and it is recommended that the Health Effects Division adopt the EDWC generated from the modeling in this assessment. Surface water and groundwater monitoring data indicated that aldicarb and its degradates were monitored since February 1986 to December 2014. Based on the analysis of the data, even with the mitigation implemented in 2009, there is no discerning trend of decline in concentrations in groundwater.

The groundwater EDWCs are less than those for surface water; therefore, it is recommended that the EDWCs for surface water be used in dietary assessments conducted by the Health Effects Division. The highest one-in-ten year peak, annual mean, and 30-year mean EDWCs (187, 16, and 5.3 µg/L, respectively) are based on the labeled use of aldicarb on sugar beets at 4.05 lbs a.i./acre per year (MN Sugar Beets). Please note that the application rates for modeling inputs on SWCC and PRZM-GW are different due to application instructions on the label. Application rate for PRZM-GW was based on the highest application rate that is allowed for labeled use in sugar beets but the granules have to be covered with soil or drilled to a specified soil depth. Meanwhile, the application rate used for SWCC modeling was the highest rate for sugar beets that can be applied without soil cover, which significantly increases the risks of surface water exposure. The scenario that provided the lowest EDWC was surface water in California (CA cotton PRZM scenario) after application of the rate used for cotton (CA Cotton). Results are summarized in Table 3.

Table 3. Screening-Level TTR EDWCs for Proposed Uses of Aldicarb [A]				
	Use Site (Max. Annual App. Rate)	**1-in-10-year**		**30-Year Mean**
Source (Model)		**Peak (µg/L)**	**Annual Mean (µg/L)**	
Surface water (SWCC)	Sugar beets (4.05 lbs a.i./A)[B]	**187**	16	5.3
	Cotton (1.05 lbs ai/A at Planting; 2.1 lbs ai/A Side Dress)[C]	23.1	1.75	0.45
		Peak	**Post-Breakthrough Average**	
Ground water (PRZM-GW) (pH 6)	Sugar beets (4.95 lbs a.i./A)[B]	93.2	**40**	

[A] Maximum values in bold.
[B] Application rates are different for both surface and ground water modeling because application instructions on the label specified that the 4.95 lbs a.i./A rate is covered with soil, thus minimizing surface runoff exposure, while 4.05 lbs a.i./A is the highest application rate that can be applied over irrigation furrow without soil cover, which increases potential surface water exposure.
[C] Use site that resulted in the lowest EDWC for aldicarb.

The entire 30-year distribution of estimated daily concentrations in surface water obtained for the MN Sugar beet and CA Cotton scenarios was incorporated into DEEM-FCID and used in the acute probabilistic analyses. The drinking water models and their descriptions are available at the EPA internet site: http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.

V. DEEM-FCID Program and Consumption Information

Aldicarb acute dietary exposure assessments were conducted using the DEEM-FCID, Version 3.16, which incorporates 2003-2008 consumption data from USDA's NHANES/WWEIA. The data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g., apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For acute exposure assessment, consumption data are retained as individual consumption events. Based on analysis of the 2003-2008 WWEIA consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50-99 years old.

For an acute exposure assessment, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for analyses performed at all levels of refinement. However, for deterministic assessments, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

The acute adverse effect of red blood cell cholinesterase inhibition tends to reverse itself within 2 hours following exposure to aldicarb. Since the food diaries used by DEEM-FCID (Version 3.16) Model are based on total daily intake, the estimated risks produced by this software are overestimates, to the extent that foods and drinking water are consumed throughout the day, rather than during only one event. To provide a better approximation of the potential exposure leading to peak RBC ChE inhibition, potential exposure from food and/or water to aldicarb was computed incrementally throughout the day. This computation was made by incorporating information on the time of day and amounts consumed during each occasion from the USDA NHANES/WWEIA food diaries. The potential for accumulation of toxicity was accounted for by computing the degree to which exposures could be discounted between exposure occasions, assuming a two-hour half-life. Further discussion of the methodology used to compute the

exposure based on the eating and drinking occasions may be found in a 2006 memo by S. Nako (D299889, 11/1/2006).

VI. Toxicological Information

The Agency evaluated the toxicity profile for aldicarb and considered the human acute oral study to be appropriate for assessment of the acute dietary exposure and risks, refer to Aldicarb Human Health Risk Assessment for the evaluation of EPA's Human Studies Review Board (D424564, *In Progress*). A chronic assessment was not conducted because the toxicity database for aldicarb indicates that cholinesterase inhibition is the most sensitive effect found, the magnitude of cholinesterase inhibition does not increase with continued exposure, and that cholinesterase inhibition is generally reversible within 24 hours at the levels relevant to the dietary risk assessment. The longer-term exposures could be considered as a series of acute exposures, with regard to cholinesterase inhibition. All other effects noted in the sub-chronic and chronic toxicity studies were observed at higher doses. Aldicarb is classified as not likely to be carcinogenic to humans.

A Comparative Cholinesterase Assay (CCA) was used to modify the Food Quality Protection Act (FQPA) factor for aldicarb (L. Taylor, 7/13/10, D376136). The acute adverse effect of cholinesterase inhibition tends to reverse itself within hours following exposure to aldicarb. The available toxicological data indicates that aldicarb has an estimated half-life for RBC ChE inhibition of two hours based on data from rats and human subjects. A summary of the doses and endpoints relevant to dietary exposure assessment are shown in Table 4 below.

Table 4. Summary of Toxicological Doses and Endpoints for Aldicarb for Use in Dietary Exposure Risk Assessments				
Exposure Scenario	**Point of Departure**	**Uncertainty/ FQPA Safety Factors** [1]	**RfD, PAD, Level of Concern**	**Study and Toxicological Effects**
Acute Dietary: (All Populations)	$BMDL_{10}$ = 0.013 mg/kg	FQPA SF = 4.8X UF_H = 10 UF_A= 1x	Acute RfD = aPAD = 0.00027 mg/kg/day	Human oral study MRIDs. 43829602, 45068601, 43442302, 43442305, 42373001 BMD_{10} = 0.02 mg/kg, based on RBC cholinesterase inhibition
Chronic Dietary: (All Populations)	A quantitative chronic assessment was not conducted because the toxicity database for aldicarb indicates that the magnitude of ChEI does not increase with continued exposure, due to the reversibility of ChEI (< 24 hours). There are no chronic toxic effects more sensitive than ChEI.			
Cancer	Classification: Aldicarb is classified as "Not Likely to be Carcinogenic to Humans", based on the lack of evidence of carcinogenicity in studies in rats and mice and the absence of a mutagenicity concern.			

ChEI = acetylcholinesterase inhibition. Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk

associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). BMD_{10} = Benchmark Dose; dose that corresponds to 10% response in ChEI. $BMDL_{10}$ = Benchmark Dose estimate based on the lower 95% confidence interval where 10% ChEI would be observed. FQPA SF = FQPA Safety Factor. PAD = population adjusted dose. a = acute. RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

VII. Results/Discussion

As stated above, for acute assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID analyses estimate the dietary exposure and risk of the U.S. population and various population subgroups. The results reported in Table(s) 5, 6, and 7 are for the general U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, adults 20-49, and adults 50-99 years. Acute assessments were conducted for food only (Tables 5 and 6), drinking water only (Attachment 3.b.), and food and drinking water (Table 6).

A preliminary screening showed that the acute dietary exposure estimates from food alone was above HED's level of concern (i.e. >100 % of the aPAD) at the 99.9[th] percentile of exposure. The commodity with highest contribution to the risk was potato which do not have domestic uses currently registered. PDP data for potato has contribution from domestic and imported samples. This data was modified to eliminate contribution from domestic samples (refer to Section VII for additional discussion). An acute dietary assessment using only detects from samples of imported potatoes results in risks below the level of concern (<100 % of the aPAD).

Exposures are above the level of concern (LOC) for drinking water only. Dietary exposure estimates ranged from 1,400% to 2,900%, and 150% to 340% of the aPAD at the 99.9[th] percentile of exposure for the general population and most population subgroups using the scenarios that resulted in the highest EDWC (MN sugar beets) and lowest EDWC (CA Cotton), respectively. Similarly, for food and drinking water, the dietary exposure is above HED's LOC using drinking water scenarios that provided the highest EDWC (MN sugar beets), see Table 6.

Table 5. Results of Acute Dietary (Food with Imported Potatoes Only) Exposure and Risk Analysis.							
Population Subgroup	aPAD (mg/kg/day)	95th Percentile		99th Percentile		99.9th Percentile	
		Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% aPAD
General U.S. Population		0.000006	2.2	0.000024	8.7	0.000067	25
All Infants (<1 year old)		0.000023	8.5	0.000043	16	0.000089	33
Children 1-2 years old*		0.000012	4.6	0.000071	26	**0.000177**	**65**
Children 3-5 years old		0.000010	3.6	0.000053	20	0.000133	49
Children 6-12 years old	0.00027	0.000005	2.0	0.000032	12	0.000076	28
Youth 13-19 years old		0.000003	1.3	0.000022	8.0	0.000050	18
Adults 20-49 years old		0.000004	1.6	0.000020	7.2	0.000044	16
Adults 50-99 years old		0.000007	2.8	0.000022	8.1	0.000049	18
Females 13-49 years old		0.000004	1.6	0.000020	7.0	0.000046	17

* The population with the highest risk estimate is in bold.

Table 6. Summary of Acute Dietary (Food Only, and Food and Drinking Water) Exposure and Risk for Aldicarb at the 99.9th Percentile of Exposure.

Population Subgroup	Water Only for CA Cotton Scenario		Water Only for MN Sugar Beets Scenario		Food and Water for MN Sugar Beets Scenario	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% aPAD
General U.S. Population	0.000492	180	0.004616	1700	0.004607	1700
All Infants (<1 year old)*	0.000909	**340**	0.007775	**2900**	0.007723	**2900**
Children 1-2 years old	0.000743	280	0.006928	2600	0.006976	2600
Children 3-5 years old	0.000628	230	0.005760	2100	0.005750	2100
Children 6-12 years old	0.000446	170	0.004206	1600	0.004220	1600
Youth 13-19 years old	0.000396	150	0.003696	1400	0.003664	1400
Adults 20-49 years old	0.000501	190	0.004677	1700	0.004672	1700
Adults 50-99 years old	0.000448	170	0.004186	1600	0.004155	1500
Females 13-49 years old	0.000498	180	0.004688	1700	0.004677	1700

* The population with the highest risk estimate is in bold.

VIII. Characterization of Inputs/Outputs

HED has conducted mostly refined acute dietary exposure and risk assessments for aldicarb and its metabolites. The assumption with respect to food made in this acute dietary assessment include the latest PDP monitoring data, anticipated residues, empirical processing factors, default DEEM processing factors, and percent crop treated when available. Moreover, the percent of commodity imported was considered for potato, grapefruit, lemons, oranges, coffee and pecans. Dietary assessments for food plus drinking water and drinking water only show that drinking water was a main driver for the U.S. general population and all population subgroups. These factors resulted in the acute aggregate (food and drinking water) dietary exposure estimates to be above HED's level of concern.

A screening for food only showed risk of concern; therefore, a critical exposure contribution analysis was conducted. This analysis showed that risks of concern for food only were mainly associated with consumption of potato tuber. PDP data for potato used in this dietary assessment was generated from 2006 to 2009. Because the use of aldicarb on potato was eliminated from the U.S.A. label on August 16, 2010 (EPA Reg. No. 264-330, label currently inactive), the PDP data used represents domestic and imported potatoes treated with aldicarb. To refine the dietary exposure, a dietary assessment was done for food only considering only the detected samples from imported potato, see Table 6. This analysis was prepared by modifying the two RDF files for potato, with and without peel, to include only the samples of potato that were imported. USDA PDP analyzed 31 samples of imported potato with peel (2008 and 2009 monitoring) resulting in one detect, and 318 samples of imported frozen potatoes without peel (2006 and 2007 monitoring) resulting in zero detects. The percent of imported potatoes with peel that were analyzed (2%) is smaller than the percent of imports reported by BEAD (8%) while the percent of imported frozen potatoes without peel that were analyzed is identical to that reported by BEAD (21%). Overall, HED understand that these RDF files are more representative of the current situation than those that include the results of domestic samples. This refinement results in a dietary risk for food only below the level of concern, 25% of the aPAD for the general

population, and 65% of the aPAD for children 1-2 years old, the highest exposed population subgroup.

Overall, the dietary assessments for food only could be refined if percent of crop treated data for the imported commodities were available. Although dietary risk estimates for food are below HED's level of concern, note that drinking water is the main contributor to the dietary exposure, as such, it has to be considered in aggregate dietary assessment in support of domestic uses of aldicarb. For measures to address the dietary risk associated with residues of aldicarb in drinking water refer to EFED memo (E. Wong, D427697, 06/17/2015). Mitigation measures discussed in 2010 (revocation of tolerances for pecan, sorghum and sugarcane, and removing uses on citrus and potato) may be necessary to accommodate exposure to drinking water as deemed necessary.

The results of a DEEM-FCID acute dietary risk assessment vary due to the random selection of residues performed during the Monte Carlo procedure. Dietary exposures at the per capita 99.9^{th} percentile may vary between 1% and 3% when different random seeds are used in a DEEM-FCID acute assessment. This effect generally differs for different subpopulations: e.g., the results for infants may increase, while the results for children 1-2 years old decrease. Those slight variations often lead to the unintuitive result that aggregate Food + Drinking Water dietary exposure estimates are lower than exposure estimates for Drinking Water alone for particular subgroup(s). We are most likely to observe such results when food provides relatively small contributions among high-end outcomes. The relative contributions from Food can be assessed by a detailed inspection of all high-end person-day outcomes (99.9^{th} – 100th percentiles), or indirectly inferred when the results for Food + Drinking Water are similar to the results for drinking water alone, as is the case for aldicarb-MN Sugar beets.

IX. Commodity Specific Analysis

Commodity specific analysis (CSA) was conducted for aldicarb to obtain estimates of the acute exposure and risk following a single consumption event for potatoes and for sweet potatoes. Dietary exposures were calculated using typical serving sizes for amounts consumed and USDA PDP monitoring data. While aldicarb is no longer used domestically on potatoes, tolerances remain in place which allows import into the U.S. of potatoes containing aldicarb residues. Dietary exposures were expressed as a percent of the acute population adjusted dose (0.00027 mg/kg/day).

Table E.2 summarizes the commodity specific analysis for aldicarb. The highest %aPAD were for pre-school age children eating the equivalent of one average size potato (130% aPAD) or sweet potato (300% aPAD). This CSA is considered a highly refined assessment for the following reasons:

- The aPAD was calculated using:
  - an endpoint/NOAEL from a human study (the inter-species factor was reduced to 1X),
  - a 4.8X **data-derived** factor for children, and
  - a 10X intra-species factor;

- PDP monitoring data were used to estimate residues, and processing/cooking data was considered, as appropriate.

A cooking factor of 1x was applied based on empirical data. Although processing factors of 0.5 (boiled, canned:cooked, canned:boiled) and 0.62 (fried) are available for sweet potato or potato, these do not apply to cooked baked sweet potato. Also, because aldicarb is applied as a soil-incorporated, granular formulation, residues may be significantly higher in individual potatoes or sweet potatoes relative to residues measured in the PDP samples, which are composites of many individual potatoes, i.e., the composite samples represent an average residue in all of the potatoes in the analyzed sample, whereas all of the residue may actually be present in only a subset of the individual potatoes. In fact, limited residue data available indicate that residues of aldicarb and its metabolites in the individual samples could be at least 2.4 times that of the composite sample suggesting that the CSA risk estimates may underestimate actual risks from consumption of individual potatoes or sweet potatoes.

For these reasons, the conservative inputs used to estimate the aldicarb CSA risks should be considered marginal, with risk estimates closely approximating actual potential risks to the small portion of the U.S. population consuming commodities containing residues at these levels.

Sweet Potato

The PDP monitoring data (2008-2010) for sweet potatoes show two detects, 0.07784 ppm and 0.06894 ppm of 1476 samples of unpeeled sweet potato, that are above the threshold (i.e. residue level that would result in risk at the level of concern) for preschoolers (0.026 ppm). PDP monitoring data is available for sweet potato baby food which showed no detects above the limit of detection of 0.0083 ppm. This results in exposures below the level of concern for infants, 24% of the aPAD. The dietary exposure is above HED's level of concern (i.e. >100% of the aPAD) for preschoolers consuming one medium size sweet potato (157 g); exposure is 300% of the aPAD. Exposures are below the level of concern for adults consuming one medium size sweet potato (75% of the aPAD).

Potato

PDP monitoring data for imported potatoes were used in the CSA; domestically cultivated potato data from 2006-2009 PDP monitoring were excluded since aldicarb is not registered for use in the U.S. as part of the 2010 mitigation. PDP monitoring data generated after cancelation of the U.S.A. use on potato is not available at this time. The dietary exposure do not exceed the level of concern for infants (100% of the aPAD) consuming ½ medium size potato (71 g), is above HED's level of concern for preschoolers (130% of the aPAD) consuming one medium size sweet potato (142 g), and is below the level of concern for adults consuming 1 medium size potato (33% of the aPAD).

X. Conclusions

Risks are below the level of concern for food only after refinement considering PDP data for imported potatoes; however, the commodity specific analysis results in exposure estimates above

100% of the aPAD following consumption of an estimated single serving of sweet potato and potatoes. The aggregate (food and drinking water) acute analysis demonstrate that the registered uses for aldicarb result in risk of concern for the general U.S. population and all population subgroups. Overall, the dietary risk is mainly associated with drinking water; refer to EFED memo for mitigation measures and Attachment 4 for estimates of drinking level of comparison. HED is confident that the assessment does not underestimate risk to the general U.S. population or any population subgroup.

XI. List of Attachments

Attachment 1. Data and Residue Estimates Used in the Dietary Exposure Analyses
Attachment 2. SLUA for Aldicarb
Attachment 3. Aldicarb Input and Result Files
Attachment 4. EDWC at the LOC Considering Exposure through Drinking Water Only
Attachment 5. Commodity Specific Analysis Conducted for Aldicarb

Attachment 1. Data and Residue Estimates Used in the Dietary Exposure Analyses

Table A.1.1. Summary of PDP Data for Aldicarb and its Sulfone and Sulfoxide Metabolites.*							
Number of Samples Analyzed							
Commodity	2006	2007	2008	2009	2010	2011	2012
Potato w/peel uncooked			744	744			
Potato w/o peel frozen	744	800					
Sweet Potato			184	739	533		
Sweet Potato Baby Food					191	585	
Orange				744	744		
Orange Juice					191	199	330

* The three residues of concern were measured in each sample.

A.1.2. PDP Data for Select Commodities						
	PDP Total Samples			PDP Total Detects		
Commodity	Total	Domestic	Imports or Unknown	Total	Domestic	Imports or Unknown
Potato (2008, 2009)	1488	1457	31	62	61	1
Potato-Frozen (2006, 2007)	1544	1226	318	93	93	0
Sweet Potatoes (2008, 2009, 2010)	1476	1458	18	5	4	1
Sweet Potatoes baby food (2010, 2011)	776	771	5	0	0	0
Oranges (2009, 2010)	1488	1365	123	5	4	0
Grapefruit (2005, 2006)	1462	1441	21	5	5	0

Table A.1.3. Data and Residue Estimates Used in the Dietary Exposure Analyses.

RAC	Food Forms	Blending Classif-ication[1]	Data Source[2]	No. of Samples	No. of Detectable Residues[3]	½ LOD	%CT[4] or % Import*	Processing Factors	Anticipated Residue Estimates/Tolerance Acute (Tol., AR, RDF)[2]
Potato, chips Potato, fried	All	B	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*	0.62	0.000437 (Import)
Potato, dry	All	B	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*	6.5	0.000437 (Import)
Potato, dry, baby food (bf)	All	B	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*	6.5	0.000437 (Import)
Potato, flour	All	B	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*	6.5	0.000437 (Import)
Potato, flour bf	All	B	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*	6.5	0.000437 (Import)
Potato, tuber, w/peel	Boiled	NB	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*	0.5	RDF 1
	Canned :Cooked; Canned :Boiled	PB	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	41*	0.5	RDF 14
	All Others	PB/NB	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*		RDF 1
Potato, tuber, w/peel bf	Canned:Cooked	PB/NB	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*	0.5	RDF 1
Potato, tuber, w/o peel	Boiled; Canned:Cooked; Canned :Boiled	PB/NB	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*	0.5	RDF 1
	Frozen Baked (FB) Frozen Fried	PB/NB	PDP Potato w/o peel 2006/2007	1544	93/0	0.0041	21*		RDF 2

	All Others	PB/NB	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*		RDF 1
Potato, tuber, w/o peel, bf	Cooked :Canned	PB/NB	PDP Potato w/peel 2008/2009	1488	62/1	0.0052	8*	0.5	RDF 1
Sweet potato	Boiled; Canned :Cooked; Canned :Boiled	PB/NB	PDP Sweet potato 2008-2010	1476	5	0.0109	100	0.5	RDF 3
	All Others	PB/NB	PDP Sweet potato 2008-2010	1476	5	0.0109	100		RDF 3
Sweet potato, bf	Cooked :Fresh	PB/NB	PDP Sweet potato 2010/2011	776	0	0.0083	100		RDF 4
	Cooked :Canned	PB/NB	PDP Sweet potato 2010/2011	776	0	0.0083	100	0.5	RDF 4
Soybean, seed	All	B	FTD D299883				2.5		0.00855 Mean 0.000214 AR
Soybean, soy milk	All	B	FTD D299883				2.5		0.00855 Mean 0.000214 AR
Soybean, soy milk, bf	All	B	FTD D299883				2.5		0.00855 Mean 0.000214 AR
Soybean, oil	All	B	FTD D299883				2.5	0.3	0.00855 Mean 0.000214 AR
Soybean, oil, bf	All	B	FTD D299883				2.5	0.3	0.00855 Mean 0.000214 AR
Soybean, flour	All	B	FTD D299883				2.5		0.00855 Mean 0.000214 AR
Soybean, flour, bf	All	B	FTD D299883				2.5		0.00855 Mean 0.000214 AR
Bean, black, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Bean, broad, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR

Bean, cowpea, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Bean, great northern, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Bean, kidney, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Bean, lima, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Bean, mung, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Bean, navy, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Bean, pink, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Bean, pinto, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Chickpea, seed	Baked, boiled, fried, canned:cooked; canned:boiled; cooked:NS	B	FTD D299883				2.5	0.05	0.00855 Mean 0.000214 AR
Orange	All	NB/PB	PDP Orange 2009/2010	1488	4	0.0131	8*		RDF 9_O_Modif 8 Perc Imports
Orange, juice	All	PB	PDP Orange Juice 2010/ 2011/2012	1106	5	0.0042	8*		RDF 10_OJ_Modif 8 Perc Imports
Orange, juice, bf	All	PB	PDP Orange Juice 2010/ 2011/2012	1106	5	0.0042	8*		RDF 10_OJ_Modif 8 Perc Imports
Orange, peel	All	PB	PDP Orange 2009/2010	1488	4	0.0131	8*		RDF 9_O_Modif 8 Perc Imports
Lemon	All	NB/PB	PDP Orange 2009/2010	1488	4	0.0131	10*		RDF 9_O_Modif 10 Perc Lemon Imports

Lemon, juice	All	PB	PDP Orange Juice 2010/ 2011/2012	1106	5	0.0042	10*		RDF 10_OJ_Modif 10 Perc Lemon Import
Lemon, peel	All	PB	PDP Orange 2009/2010	1488	4	0.0131	10*		RDF 9_O_Modif 10 Perc Lemon Imports
Lime	All	NB	PDP Orange 2009/2010	1488	4	0.0131	100		RDF 9
Lime, juice	All	PB	PDP Orange Juice 2010/ 2011/2012	1106	5	0.0042	100		RDF 10
Lime, juice, bf	All	PB	PDP Orange Juice 2010/ 2011/2012	1106	5	0.0042	100		RDF 10
Grapefruit	All	NB/PB	PDP Orange 2009/2010	1488	4	0.0131	2*		RDF 9_O_Modif 2 Perc Grapefruit Imp
Grapefruit, juice	All	PB	PDP Orange Juice 2010/ 2011/2012	1106	5	0.0042	2*		RDF 10_OJ_Modif 2 Perc Grapefruit Imports
Pecan	All	PB	FTD D299883		22		58*		RDF 13
Sorghum, grain	All	B	Tolerance				100		0.2
Sorghum, syrup	All	B	Tolerance				100		0.2
Cottonseed, oil	All	B	FTD D425180				35	0.1	0.0453 Mean 0.0159 AR
Cottonseed, oil, bf	All	B	FTD D425180				35	0.1	0.0453 Mean 0.0159 AR
Coffee, roasted bean	All	B	FTD D299883				100		0.00855
Coffee, instant	All	B	FTD D299883				100		0.00855
Peanut	All	B	FTD D299883				45		0.0047 Mean 0.002115 AR

1. Classification: blended (B), partially blended (PB), not blended (NB).
2. Field Trial Data (FTD); Residue Distribution File (RDF); Anticipated Residue (AR); Baby food (bf); with (w); without (w/o); Orange (O); Orange Juice (OJ).

Table A.1.4. RDF Files and Point Estimate Calculations		
Refinement for Potatoes (Import Samples Only)		
RDF 1_Potato_wPeel_ Uncooked_1_Imports.rdf PDP Data: POFR (2008,2009), Total Samples=1488, Total Detects=1, Total LODs=118, Total Zeros=1369; 8% Imported Potatoes, Avg Residue (Detects)=0.083327, Avg Residue (TOTALS)=0.0085, Avg Residue Avg HLOD (NonDetects)=0.0052 TOTALZ=1369 TOTALLOD=118 LODRES=0.0052 0.03796	RDF 2_Potato_wopeel_Frozen_ Baked_2_Imports.rdf PDP Data: PZFZ (2006,2007), Total Samples=1544, Total Detects=0, Total LODs=324, Total Zeros=1220 21% of Imported Potatoes, Avg Residue (Detects)=0.011659, Avg Residue (TOTALS)=0.0045, Avg HLOD (NonDetects)=0.0041 TOTALZ=1220 TOTALLOD=324 LODRES=0.0041	Potato Blended Processed Commodities: Anticipated Residues Residue estimate for a blended processed commodity based on monitoring data and % of imports. PDP Data for Potato with Peel Uncooked: POFR (2008, 2009), Total Samples=1488, Total Detects=1, Sum of Detects=0.03796 ppm, Total LODs=118, Avg HLOD=0.0052; 8% of Imported Potatoes. Total Samples with Residues = 119 ½LOD = 0.0052 ppm Total Samples ½ LOD = 118 Sum of Detects = 0.03796 ppm Anticipated residue: 0.000437 ppm [(118 samples*0.0052 ppm + 0.03796 ppm)/1488]
RDF 14_Potato_wPeel_ Uncooked_Canned_14_Imports.rdf PDP Data: POFR (2008,2009), Total Samples=1488, Total Detects=1, Total LODs=609, Total Zeros=878; 41% Imported Potatoes, Avg Residue (Detects)=0.083327, Avg Residue (TOTALS)=0.0085, Avg Residue Avg HLOD (NonDetects)=0.0052 TOTALZ=878 TOTALLOD=609 LODRES=0.0052 0.03796		
All Other RDFs		

RDF 3_Potato_Sweet_3.rdf PDP Data: SWFR (2008,2009,2010), Total Samples=1476, Total Detects=5, Total LODs=1471, Total Zeros=0 MaxPCT=100, Avg Residue (Detects)=0.038920, Avg Residue (TOTALS)=0.0017, Avg Residue (Blended, PCT=100)=0.010967, Avg HLOD (NonDetects)=0.0109 TOTALZ=0 TOTALLOD=1471 LODRES=0.0109 0.07784 0.06594 0.02126 0.01478 0.01478	RDF 4_Potato_Sweet_4.rdf PDP Data: ISGJ,ISPC,ISSE; Baby food; (2010,2011), Total Samples=776, Total Detects=0, Total LODs=116, Total Zeros=0 MaxPCT=100, Avg Residue (Detects)=., Avg Residue (TOTALS)=0.0012, Avg Residue (Blended, PCT=100)=0.008340, Avg HLOD (NonDetects)=0.0083 TOTALZ=0 TOTALLOD=776 LODRES=0.0083	Soybean and Dry Bean: Anticipated Residues Average residue values reported in D299883 (C. Olinger, 08/16/2010) were used. The %CT for soybean and dry beans is 2.5%. Average residue: 0.00855 ppm Anticipated residue: 0.000214 ppm [0.00855 ppm x 0.025 (fraction of crop treated)]
RDF 9_Orange_9.rdf PDP Data: OGFR (2009,2010), Total Samples=1488, Total Detects=4, Total LODs=1484, Total Zeros=0; MaxPCT=1.000, Avg Residue (Detects)=0.018950, Avg Residue (TOTALS)=0.0131, Avg Residue (Blended, PCT=100)=0.013133, Avg HLOD (NonDetects)=0.0131 TOTALZ=0 TOTALLOD=1484 LODRES=0.0131 0.02126 0.02034 0.01942 0.01478	RDF 9_Orange_9_Modified_8Perc Imports.rdf PDP Data: OGFR (2009,2010), Total Samples=1488, Total Detects=4, Total LODs=115, Total Zeros=1369; 8% Imports, Avg Residue (Detects)=0.018950, Avg Residue (TOTALS)=0.0131, Avg HLOD (NonDetects)=0.0131 TOTALZ=1369 TOTALLOD=115 LODRES=0.0131 0.02126 0.02034 0.01942 0.01478	RDF 9_Orange_9_Modified _10Perc Lemon Import.rdf PDP Data: OGFR (2009,2010), Total Samples=1488, Total Detects=4, Total LODs=145, Total Zeros=1339; 10% Imports, Avg Residue (Detects)=0.018950, Avg Residue (TOTALS)=0.0131, Avg HLOD (NonDetects)=0.0131 TOTALZ=1339 TOTALLOD=145 LODRES=0.0131 0.02126 0.02034 0.01942 0.01478
RDF 9_Orange_9_Modified_2Perc Grapefruit Import.rdf PDP Data: OGFR (2009,2010), Total Samples=1488, Total Detects=4, Total LODs=26, Total Zeros=1458; 2% Imports, Avg Residue (Detects)=0.018950, Avg Residue (TOTALS)=0.0131, Avg HLOD (NonDetects)=0.0131 TOTALZ=1458 TOTALLOD=26 LODRES=0.0131 0.02126 0.02034 0.01942 0.01478	RDF 10_Orange_Juice_10.rdf PDP Data: OJCO,OJFZ,OJRE (2010,2011,2012), Total Samples=1106, Total Detects=5, Total LODs=1101, Total Zeros=0 MaxPCT=1.000, Avg Residue (Detects)=0.006102, Avg Residue (TOTALS)=0.0042, Avg Residue (Blended, PCT=100)=0.004179, Avg HLOD (NonDetects)=0.0042 TOTALZ=0 TOTALLOD=1101 LODRES=0.0042 0.00647 0.00647 0.00647 0.00555 0.00555	RDF 10_Orange_Juice_10_ Modified 8Perc Imports.rdf PDP Data: OJCO,OJFZ,OJRE (2010,2011,2012), Total Samples=1106, Total Detects=5, Total LODs=83, Total Zeros=1018 8% Imports, Avg Residue (Detects)=0.006102, Avg Residue (TOTALS)=0.0042, Avg HLOD (NonDetects)=0.0042 TOTALZ=1018 TOTALLOD=83 LODRES=0.0042 0.00647 0.00647 0.00647 0.00555 0.00555

RDF 10_Orange_Juice_10_ Modified_10Perc Lemon Imports.rdf	RDF 10_Orange_Juice_10_ Modified_2Perc Grapefruit Imports.rdf	RDF 13_Pecan_13.rdf
PDP Data: OJCO,OJFZ,OJRE (2010,2011,2012), Total Samples=1106, Total Detects=5, Total LODs=106, Total Zeros=995; 10% Imports, Avg Residue (Detects)=0.006102, Avg Residue (TOTALS)=0.0042, Avg HLOD (NonDetects)=0.0042 TOTALZ=995 TOTALLOD=106 LODRES=0.0042 0.00647 0.00647 0.00647 0.00555 0.00555	PDP Data: OJCO,OJFZ,OJRE (2010,2011,2012), Total Samples=1106, Total Detects=5, Total LODs=17, Total Zeros=1084, 2% Imports, Avg Residue (Detects)=0.006102, Avg Residue (TOTALS)=0.0042, Avg HLOD (NonDetects)=0.0042 TOTALZ=1084 TOTALLOD=17 LODRES=0.0042 0.00647 0.00647 0.00647 0.00555 0.00555	Pecan Aldicarb FTD; 22 Samples Field Trial Residue Data [MRID No. 102123] 58% Imported Pecan TOTALZ=16 4,0.0043 2,0.0171 2,0.0256 2,0.0427 2,0.00855 0.0342 0.0684 0.0598 0.0513 0.0769 0.0940 0.0855 0.231 0.103 0.145
Cotton seed oil: Anticipated Residues Residue estimate for a blended commodity based on crop field trial data. Mean residue: 0.0453 ppm Anticipated residue: 0.0159 ppm [0.0453 ppm x 0.35 (fraction of crop treated)]		

Attachment 2. Import Usage and SLUA for Aldicarb

A.2.1. Import Usage for Commodities with Tolerances and No U.S.A. Registration

The following report was provided by the Biological and Economic Analysis Divison (D. Atwood, e-mails received on 11/25/2015 and on 12/28/2015).

Aldicarb Import Usage (Average 2009-2013)						
	US Production (million lbs)	Commodity Export (million lbs)	Available domestic (million lbs)	Commodity Imports (million lbs)	Total Available for consumption (million lbs)	% Import Component
Grapefruit	1,304.8	489.2	815.6	20	835.6	2%
Lemons	1155.2	210.6	944.6	100.8	1,045.4	10%
Limes	0	6	-6.0	833.8	827.8	101%*
Orange	4289.2	1449.3	2,839.9	245.1	3,085.0	8%
Pecans	133753	75107	58646	82459	141105	58%
Coffee	7.8	388.2	-380.4	3359.7	2979.3	113%*
Potatoes	11010	972	10038	910	10948	8%
Citrus dry pulp	Data not available					
Sorghum, grain, bran	Data not available					
Sorghum, grain, grain	Data not available					
Sorghum, grain, stover	Data not available					
Sugarcane, cane	Data not available					
Source: USDA/ERS. 2015. Food Availability (Per Capita) Data System http://www.ers.usda.gov/data-products/food-availability-(per-capita)-data-system.aspx#.Up9c9dLkvMY						

* For limes and coffee, a 100% of import component was used for dietary assessment purposes.

	US Production (million lbs)	Commodity Export (million lbs)	Available domestic (million lbs)	Commodity Imports (million lbs)	Total Available for consumption (million lbs)	% Import Component
Potatoes (Fresh)	11020.1	923.2	10096.9	915.2	11012.1	8%
Potaotes (Freezing)	15744.4	3707.6	12036.8	3285.7	15322.5	21%
Potatoes (Canning)	239.3	106.2	133.1	91.9	225	41%
Potatoes (Chips)	5411.3	461.3	4950	106.9	5056.9	2%
Potaotes (Dehydrated)	4364	1114.7	3249.3	532.9	3782.2	14%
Potatoes (Total)	36779.2	6313.1	30466.1	4932.6	35398.7	14%

A.2.2. Screening Level Usage Analysis for Aldicarb

Aldicarb (098301)
Screening Level Usage Analysis (SLUA)
Date: December 18, 2014

What is a Screening Level Usage Analysis (SLUA)?
- Available estimates of pesticide usage data for a particular active ingredient that is used on **agricultural** crops in the United States.
- Pesticide usage data obtained from various sources. The data are then merged, averaged, and rounded so that the presented information is not proprietary, business confidential, or trade secret.

What does it contain?
- Pesticide usage data for a **single** active ingredient only.
- Agricultural use sites (crops) that the pesticide is *reported* to be used on.
- Available pesticide usage information from U.S. states that produce 80% or more of a crop, in most cases, or less than 80%, in rare cases, depending on the scope of the survey and available resources.
- Annual percent of crop treated **(average & maximum)** for each agricultural crop.
- Average annual pounds of the pesticide applied for each agricultural crop (i.e., for the states surveyed, not for the entire United States).

What assumptions can I make about the reported data?
- **Average pounds of active ingredient applied** - Values are calculated by merging pesticide usage data sources together; averaging across all observations, then rounding. *Note: If the estimated value is less than 500, then that value is labeled <500. Estimated values between 500 & <1,000,000 are rounded to 1 significant digit. Estimated values of 1,000,000 or greater are rounded to 2 significant digits.)*
- **Average percent of crop treated** - Values are calculated by merging data sources together; averaging by year, averaging across all years, & rounding to the nearest multiple of 5. *Note: If the estimated value is less than 2.5, then the value is labeled <2.5. If the estimated value is less than 1, then the value is labeled <1.*
- **Maximum percent of crop treated** - Value is the single maximum value reported across all data sources, across all years, & rounded up to the nearest multiple of 5. *Note: If the estimated value is less than 2.5, then the value is labeled <2.5.*

What are the data sources used?
- **USDA-NASS** (United States Department of Agriculture's National Agricultural Statistics Service) – pesticide usage data from 2004 to 2012.
- **Private pesticide market research** – pesticide usage data from 2004 to 2012.
- **California Department of Pesticide Regulation (DPR) Pesticide Use Reporting (PUR)** data for 2004 to 2011.

What are the limitations to the data?
- Additional registered uses may exist but are not included because the available surveys do not report usage (e.g., small acreage crops).
- Lack of reported usage data for the pesticide on a crop **does not imply** zero usage.
- Usage data on a particular site may be noted in data sources, but **not quantified**. In these instances, the site would not be reported in the SLUA.

- Non-agricultural use sites (e.g., turf, post-harvest, mosquito control, etc.) are not reported in the SLUA. A separate request must be made to receive these estimates.
- Some sites show some use, even though they are not on the label. This usage could be due to various factors, including, but not limited to Section 18 requests, existing stocks of the chemical, data collection errors, and experimental use permits (EUPs).

December 18, 2014

Screening Level Estimates of Agricultural Uses of Aldicarb (098301)
Sorted Alphabetically
(Reporting Timeframe: 2004-2012)

	Crop	Average Lbs. A.I.	Percent Crop Treated	
			Average	Maximum
1	Almonds+	2,000	<1	<2.5
2	Cantaloupes+	<500	<1	<2.5
3	Cotton	1,600,000	20	35
4	Dry Beans/Peas	10,000	<2.5	<2.5
5	Grapefruit+	100,000	35	55
6	Lemons+	<500	<1	<2.5
7	Oranges+	500,000	15	35
8	Peanuts	400,000	35	45
9	Pecans+	10,000	<2.5	<2.5
10	Potatoes+	200,000	5	15
11	Sorghum+	2,000	<1	<2.5
12	Soybeans	60,000	<1	<2.5
13	Sugar Beets	100,000	5	10
14	Sugarcane+	7,000	<2.5	<2.5
15	Tangerines+	6,000	5	5
16	Tobacco+	20,000	5	10
17	Watermelons+	<500	<1	<2.5

All numbers rounded.
   <500   Less than 500 pounds of active ingredient
   <2.5   Less than 2.5 percent of crop treated
    <1   Less than 1 percent of crop treated

    +   There is no current active registration for this use.

SLUA data sources include:
    USDA-NASS (United States Department of Agriculture's National Agricultural Statistics Service)
    Private Pesticide Market Research

These results reflect amalgamated data developed by the Agency and are releasable to the public.

Attachment 3. Aldicarb Input and Result Files

A) Input File for Food (Refined Potato Imports) + Drinking Water (Sugar beet)

```
Filename: C:\Users\IEncarna\Dietary Assessments\Aldicarb\DEEM Files\Aldicarb Acute_Food
Water SugarBeet_Refined_PotatoImports.r08
Chemical: Aldicarb Acute Dietary Assessment
RfD(Chronic): 0 mg/kg bw/day  NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): .00027 mg/kg bw/day  NOEL(Acute):  0 mg/kg bw/day
Date created/last modified: 02-18-2016/10:43:52       Program ver. 3.16, 03-08-d
-------------------------------------------------------------------------------
RDL indices and parameters for Monte Carlo Analysis:
Index Dist Parameter #1         Param #2  Param #3  Comment
  #   Code
----- ---- ------------         -------- --------  -------
  1    6    C:\Users\IEncarna\Dietary
Assessments\Aldicarb\Scenario2\Potato_wPeel_Uncooked_1_Imports.rdf
  2    6    C:\Users\IEncarna\Dietary
Assessments\Aldicarb\Scenario2\Potato_wopeel_Frozen_Baked_2_Imports.rdf
  3    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Potato_Sweet_3.rdf
  4    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Potato_Sweet_BF_4.rdf
  5    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Orange_9_Modified 8Perc
Import.rdf
  6    6    C:\Users\IEncarna\Dietary
Assessments\Aldicarb\Scenario2\Orange_Juice_10_Modified 8 Perc Imports.rdf
  7    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Orange_9_Modified
10Perc Lemon Import.rdf
  8    6    C:\Users\IEncarna\Dietary
Assessments\Aldicarb\Scenario2\Orange_Juice_10_Modified 10 Perc Lemon Imports.rdf
  9    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Orange_9.rdf
 10    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Orange_Juice_10.rdf
 11    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Orange_9_Modified 2Perc
Grapefruit Import.rdf
 12    6    C:\Users\IEncarna\Dietary
Assessments\Aldicarb\Scenario2\Orange_Juice_10_Modified 2 Perc Grapefruit Imports.rdf
 13    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Pecan_FTD_13.rdf
 14    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Aldicarb_SWCC_pH7_MN
Sugarbeets_12.rdf
 15    6    C:\Users\IEncarna\Dietary Assessments\Aldicarb\Scenario2\Potato_wPeel_Uncooked
Baked_14_Imports.rdf
```

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	#2	RDLComment Pntr
0103296000	1C	Potato, chips	0.000437	0.620	1.000	
0103297000	1C	Potato, dry (granules/ flakes)	0.000437	6.500	1.000	
0103297001	1C	Potato, dry (granules/ flakes)-b	0.000437	6.500	1.000	
0103298000	1C	Potato, flour	0.000437	6.500	1.000	
0103298001	1C	Potato, flour-babyfood	0.000437	6.500	1.000	
0103299000	1C	Potato, tuber, w/peel				
		110-Uncooked; Fresh or N/S; Cook Meth N/S				
			1.000000	1.000	1.000	1
		210-Cooked; Fresh or N/S; Cook Meth N/S				
			1.000000	1.000	1.000	1
		211-Cooked; Fresh or N/S; Baked				
			1.000000	1.000	1.000	1
		212-Cooked; Fresh or N/S; Boiled				
			1.000000	0.500	1.000	1
		213-Cooked; Fresh or N/S; Fried				
			1.000000	0.620	1.000	1
0103299001	1C	Potato, tuber, w/peel-babyfood	1.000000	1.000	1.000	1
0103300000	1C	Potato, tuber, w/o peel				
		110-Uncooked; Fresh or N/S; Cook Meth N/S				

```
                                              1.000000  1.000  1.000    1
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                              1.000000  1.000  1.000    1
                  211-Cooked; Fresh or N/S; Baked
                                              1.000000  1.000  1.000    1
                  212-Cooked; Fresh or N/S; Boiled
                                              1.000000  1.000  1.000    1
                  213-Cooked; Fresh or N/S; Fried
                                              1.000000  0.500  1.000    1
                  221-Cooked; Frozen; Baked   1.000000  0.620  1.000    1
                  223-Cooked; Frozen; Fried   1.000000  1.000  1.000    2
                  232-Cooked; Dried; Boiled   1.000000  0.620  1.000    1
                  233-Cooked; Dried; Fried    1.000000  0.500  1.000    1
                  240-Cooked; Canned; Cook Meth N/S  1.000000 0.620 1.000 1
                                              1.000000  0.500  1.000   15
                  242-Cooked; Canned; Boiled  1.000000  0.500  1.000   15
                  252-Cooked; Cured etc; Boiled 1.000000 0.500 1.000    1
0103300001 1C   Potato, tuber, w/o peel-babyfood
                  240-Cooked; Canned; Cook Meth N/S
                                              1.000000  0.500  1.000    1
0103366000 1CD  Sweet potato
                  210-Cooked; Fresh or N/S; Cook Meth N/S
                                              1.000000  1.000  1.000    3
                  211-Cooked; Fresh or N/S; Baked
                                              1.000000  1.000  1.000    3
                  212-Cooked; Fresh or N/S; Boiled
                                              1.000000  0.500  1.000    3
                  213-Cooked; Fresh or N/S; Fried
                                              1.000000  0.620  1.000    3
                  215-Cooked; Fresh or N/S; Boiled/baked
                                              1.000000  1.000  1.000    3
                  240-Cooked; Canned; Cook Meth N/S
                                              1.000000  0.500  1.000    3
                  242-Cooked; Canned; Boiled  1.000000  0.500  1.000    3
0103366001 1CD  Sweet potato-babyfood
                  211-Cooked; Fresh or N/S; Baked
                                              1.000000  1.000  1.000    4
                  240-Cooked; Canned; Cook Meth N/S
                                              1.000000  0.500  1.000    4
0600347000 6    Soybean, seed               0.000214  1.000  1.000
0600349000 6    Soybean, soy milk           0.000214  1.000  1.000
0600349001 6    Soybean, soy milk-babyfood or in  0.000214 1.000 1.000
0600350000 6    Soybean, oil                0.000214  0.300  1.000
0600350001 6    Soybean, oil-babyfood       0.000214  0.300  1.000
0603030000 6C   Bean, black, seed           0.000214  0.050  1.000
0603032000 6C   Bean, broad, seed           0.000214  0.050  1.000
0603034000 6C   Bean, cowpea, seed
                  232-Cooked; Dried; Boiled   0.000214  0.050  1.000
0603035000 6C   Bean,  great northern, seed 0.000214  0.050  1.000
0603036000 6C   Bean, kidney, seed          0.000214  0.050  1.000
0603038000 6C   Bean, lima, seed            0.000214  0.050  1.000
0603039000 6C   Bean, mung, seed            0.000214  0.050  1.000
0603040000 6C   Bean, navy, seed            0.000214  0.050  1.000
0603041000 6C   Bean, pink, seed            0.000214  0.050  1.000
0603042000 6C   Bean, pinto, seed           0.000214  0.050  1.000
0603098000 6C   Chickpea, seed              0.000214  0.050  1.000
0603098001 6C   Chickpea, seed-babyfood     0.000214  0.050  1.000
0603099000 6C   Chickpea, flour             0.000214  0.050  1.000
0603182000 6C   Guar, seed                  0.000214  0.050  1.000
0603182001 6C   Guar, seed-babyfood         0.000214  0.050  1.000
0603348000 6C   Soybean, flour              0.000214  1.000  1.000
0603348001 6C   Soybean, flour-babyfood     0.000214  1.000  1.000
1001240000 10A  Orange                      1.000000  1.000  1.000    5
1001241000 10A  Orange, juice               1.000000  1.000  1.000    6
1001241001 10A  Orange, juice-babyfood      1.000000  1.000  1.000    6
1001242000 10A  Orange, peel                1.000000  1.000  1.000    5
1002199000 10B  Lemon                       1.000000  1.000  1.000    7
```

```
1002200000 10B  Lemon, juice                   1.000000  1.000  1.000   8
1002200001 10B  Lemon, juice-babyfood          1.000000  1.000  1.000   8
1002201000 10B  Lemon, peel                    1.000000  1.000  1.000   7
1002206000 10B  Lime                           1.000000  1.000  1.000   9
1002207000 10B  Lime, juice                    1.000000  1.000  1.000  10
1002207001 10B  Lime, juice-babyfood           1.000000  1.000  1.000  10
1003180000 10C  Grapefruit                     1.000000  1.000  1.000  11
1003181000 10C  Grapefruit, juice              1.000000  1.000  1.000  12
1400269000 14   Pecan                          1.000000  1.000  1.000  13
1500344000 15   Sorghum, grain                 0.200000  1.000  1.000
1500345000 15   Sorghum, syrup                 0.200000  1.000  1.000
2003128000 20C  Cottonseed, oil                0.015900  0.100  1.000
2003128001 20C  Cottonseed, oil-babyfood       0.015900  0.100  1.000
8601000000 86A  Water, direct, all sources     1.000000  1.000  1.000  14
8602000000 86B  Water, indirect, all sources   1.000000  1.000  1.000  14
9500115000 O    Coffee, roasted bean           0.008550  1.000  1.000
9500116000 O    Coffee, instant                0.008550  1.000  1.000
9500263000 O    Peanut                         0.002115  1.000  1.000
```

B) Result files

Food (Refined Potato Imports) and Drinking Water (Sugar beets)

```
US EPA                                                Ver. 3.18, 03-08-d
DEEM-FCID ACUTE Analysis for ALDICARB ACUTE DIETARY ASSESSMENT
                                                  NHANES 2003-2008 2-Day
Residue file: Aldicarb Acute_Food Water SugarBeet_Refined_PotatoImports.r08
Adjustment factor #2 NOT used.
Analysis Date: 03-23-2016/17:48:49    Residue file dated: 02-18-2016/10:43:52
RAC/FF intake reported by eating occasion
Reversal analysis used with half life = 2 hr(s)
MC iterations = 1000; MC list in residue file; MC seed = 155; RNG = MS VB
MC residues held constant for each RAC/FF intake on same day/iteration
Run Comment: ""
============================================================================

Summary calculations--per capita:

                95th Percentile      99th Percentile      99.9th Percentile
                Exposure  % aRfD     Exposure  % aRfD     Exposure  % aRfD
                --------- --------   --------- --------   --------- --------
Total US Population:
                0.000240    88.88    0.001356   502.11    0.004607  1706.15
All Infants:
                0.000353   130.79    0.002603   964.03    0.007723  2860.41
Children 1-2:
                0.000348   129.05    0.002022   748.86    0.006976  2583.69
Children 3-5:
                0.000304   112.76    0.001780   659.41    0.005750  2129.81
Children 6-12:
                0.000214    79.30    0.001270   470.25    0.004220  1562.94
Youth 13-19:
                0.000171    63.35    0.001051   389.20    0.003664  1356.94
Adults 20-49:
                0.000243    90.10    0.001373   508.49    0.004672  1730.31
Adults 50-99:
                0.000247    91.55    0.001299   481.03    0.004155  1538.98
Female 13-49:
                0.000239    88.39    0.001364   505.09    0.004677  1732.13
```

Food Only (Refined Potato Imports)

Result File

```
US EPA                                                        Ver. 3.18, 03-08-d
DEEM-FCID ACUTE Analysis for ALDICARB ACUTE DIETARY ASSESSMENT
                                                      NHANES 2003-2008 2-Day
Residue file: Aldicarb Acute_Food Only_Refined_PotatoImports.r08
Adjustment factor #2 NOT used.
Analysis Date: 03-24-2016/09:46:53    Residue file dated: 02-18-2016/10:46:19
RAC/FF intake reported by eating occasion
Reversal analysis used with half life = 2 hr(s)
MC iterations = 1000; MC list in residue file; MC seed = 155; RNG = MS VB
MC residues held constant for each RAC/FF intake on same day/iteration
Run Comment: ""
================================================================================
```

Summary calculations--per capita:

	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
Total US Population:						
	0.000006	2.15	0.000024	8.73	0.000067	24.99
All Infants:						
	0.000023	8.46	0.000043	16.05	0.000089	33.01
Children 1-2:						
	0.000012	4.62	0.000071	26.31	0.000177	65.47
Children 3-5:						
	0.000010	3.63	0.000053	19.70	0.000133	49.42
Children 6-12:						
	0.000005	2.01	0.000032	11.73	0.000076	28.08
Youth 13-19:						
	0.000003	1.28	0.000022	7.98	0.000050	18.48
Adults 20-49:						
	0.000004	1.64	0.000020	7.24	0.000044	16.41
Adults 50-99:						
	0.000007	2.76	0.000022	8.05	0.000049	18.14
Female 13-49:						
	0.000004	1.59	0.000020	7.24	0.000046	16.89

CEC Analysis for Food Only (Children 1-2)
```
US EPA
DEEM-FCID Acute Critical Exposure Contribution Analysis (Ver. 3.18, 03-08-d)
NHANES 2003-2008 2-Day
Residue file = C:\Users\IEncarna\Dietary Assessments\Aldicarb\DEEM Files\Aldicarb
Acute_Food Only_Refined_PotatoImports.r08
Acute report = C:\Users\IEncarna\Dietary Assessments\Aldicarb\DEEM Files\Aldicarb_Food
Only_24May2016.AC8
Date and time of analysis: 03-24-2016 09:33:19
Food and foodform consumption evaluated by eating occasion.
Adjustment factor #2 not used.
Minimum exposure contribution = 5%
MC Iterations = 1000  Seed = 155  RNG = MS VB
CEC records generated for first 812 iterations.
Exposures divided by body weight

Children 1-2
Low percentile for CEC records: 99.9   Exposure (mg/day) =   0.000177
High percentile for CEC records: 100   Exposure (mg/day) =   0.001026
Number of actual records in this interval: 2582


Critical foods with foodforms for this population (as derived from these records):
Only foods/foodforms with percent contribution >= 5 are reported.
  N=number of appearances in all records (including duplicates)
   %=percent of total exposure for all records (including duplicates)
```

```
Food          FF      N     Percent   Food Name
----------    ---   -----   -------   -------------
1001240000    110    1359   48.97%    Orange-Uncooked; Fresh or N/S; Cook Meth N/S
1001241000    110     897   33.08%    Orange, juice-Uncooked; Fresh or N/S; Cook Meth N/S
1001241000    120     291    9.20%    Orange, juice-Uncooked; Frozen; Cook Meth N/S


Critical foods (without foodforms) for this population (as derived from these records):
Only foods with percent contribution >= 5 are reported.
  N=number of appearances in all records (including duplicates)
   %=percent of total exposure for all records (including duplicates)

Food          N     Percent   Food Name
----------  -----   -------   -------------
1001240000   1359   48.97%    Orange
1001241000   1192   42.29%    Orange, juice
```

Drinking Water Only (Sugar beets)

```
US EPA                                            Ver. 3.18, 03-08-d
DEEM-FCID ACUTE Analysis for ALDICARB WATER ONLY (SUGARBEET)
                                           NHANES 2003-2008 2-Day
Residue file: Aldicarb Acute_Water Only SugarBeets.r08
Adjustment factor #2 NOT used.
Analysis Date: 03-23-2016/15:42:45    Residue file dated: 11-12-2015/11:05:07
RAC/FF intake reported by eating occasion
Reversal analysis used with half life = 2 hr(s)
MC iterations = 1000; MC list in residue file; MC seed = 155; RNG = MS VB
MC residues held constant for each RAC/FF intake on same day/iteration
Run Comment: ""
==============================================================================

Summary calculations--per capita:

                95th Percentile      99th Percentile      99.9th Percentile
                Exposure   % aRfD    Exposure   % aRfD    Exposure   % aRfD
                ---------- --------  ---------- --------   ---------- --------
Total US Population:
                0.000238    88.32    0.001353   501.17    0.004616   1709.59
All Infants:
                0.000354   131.01    0.002611   967.15    0.007775   2879.72
Children 1-2:
                0.000343   126.89    0.002007   743.50    0.006928   2566.09
Children 3-5:
                0.000303   112.15    0.001778   658.44    0.005760   2133.24
Children 6-12:
                0.000212    78.36    0.001263   467.71    0.004206   1557.62
Youth 13-19:
                0.000171    63.24    0.001051   389.14    0.003696   1368.78
Adults 20-49:
                0.000242    89.78    0.001371   507.62    0.004677   1732.14
Adults 50-99:
                0.000245    90.75    0.001293   478.94    0.004186   1550.47
Female 13-49:
                0.000237    87.94    0.001362   504.43    0.004688   1736.41
```

Drinking Water Only (Cotton)

```
US EPA                                            Ver. 3.18, 03-08-d
DEEM-FCID ACUTE Analysis for ALDICARB WATER ONLY (SUGARBEET)
```

```
                                                 NHANES 2003-2008 2-Day
Residue file: Aldicarb Acute_Water Only Cotton.r08
Adjustment factor #2 NOT used.
Analysis Date: 03-23-2016/18:09:15    Residue file dated: 11-12-2015/11:13:42
RAC/FF intake reported by eating occasion
Reversal analysis used with half life = 2 hr(s)
MC iterations = 1000; MC list in residue file; MC seed = 155; RNG = MS VB
MC residues held constant for each RAC/FF intake on same day/iteration
Run Comment: ""
===============================================================================


Summary calculations--per capita:

                    95th Percentile      99th Percentile      99.9th Percentile
                    Exposure   % aRfD    Exposure   % aRfD    Exposure   % aRfD
                    ---------- --------  ---------- --------  ---------- --------
Total US Population:
                    0.000016     5.84    0.000125    46.32    0.000492   182.24
All Infants:
                    0.000021     7.82    0.000241    89.13    0.000909   336.58
Children 1-2:
                    0.000023     8.39    0.000186    69.05    0.000743   275.23
Children 3-5:
                    0.000020     7.51    0.000165    61.04    0.000628   232.45
Children 6-12:
                    0.000014     5.12    0.000116    42.99    0.000446   165.07
Youth 13-19:
                    0.000011     4.05    0.000096    35.55    0.000396   146.73
Adults 20-49:
                    0.000016     5.91    0.000127    47.16    0.000501   185.56
Adults 50-99:
                    0.000017     6.19    0.000120    44.47    0.000448   165.94
Female 13-49:
                    0.000016     5.81    0.000126    46.65    0.000498   184.33
```

Attachment 4. EDWC at the LOC Considering Exposure through Drinking Water Only

A screening tool was used to provide an estimate of the contribution of pesticide residues in drinking water to the dietary risk of the pesticide. Rough estimates of the estimated drinking water concentration (EDWC) at the level of concern (LOC) are provided without considering contribution from food and residential exposures. Therefore, even if estimated drinking water risks are relatively low, aggregate risk may be of concern. The water consumption values were obtained using the dietary exposure and risk model, DEEM-FCID Version 4.02, which uses food consumption data from the USDA National Health and Nutrition Examination Survey, What We Eat in America, conducted from 2005 to 2010; refer to Table A.4.2. In general, the population subgroup with higher exposure to residues in drinking water is infants (<1 yr old). The equation used to estimate the dietary risk and the results of the screening are presented below.

The lowest EDWC at the level of concern is 1.5 ppb and 0.8 ppb at the 95th and 99.9[th] percentile of exposure, respectively. It is important to note that a distribution of water residues will be used for dietary assessment of aldicarb; therefore, the distribution from the modeling a scenario that results in a peak concentration similar to those estimated here is likely to result in lower dietary risk than that obtained using a point estimate.

Table A.4.1. Results of the screening of the Dietary Risk Contribution from Drinking Water

Assessment	Population	aPAD (mg/kg/day)	EDWC at LOC (ppb)	
			95th	99.9[th]
Acute	General	0.00027	5.075188	1.5
	All Infants	0.00027	1.47541	0.794118
	Females	0.00027	5.13308	2.347826

Equation to estimate the dietary risk:

$$\%aPAD, \%ssPAD \text{ or } \%cPAD \ (Water) = \frac{(Water\ Consumption, L/kgbw/day)(EDWC, ppb)}{\left(1000\ \frac{\mu g}{mg}\right)(aPAD, ssPAD \text{ or } cPAD, mg/kg/day)} \times 100$$

Table A.4.2. Water consumption (L / kg-bw*day) for Acute Analysis

Population Subgroup	Acute	
	95th	99.9[th]
General Population	0.0532	0.180
All Infants (< 1yr old)	0.183	0.340
Females (13-49 yrs)	0.0526	0.115

Attachment 5. Commodity Specific Analysis Conducted for Aldicarb.

Table A.5.1. Aldicarb PDP Monitoring Data Used for the Commodity Specific Analysis.	
Source of Data Used For Refinement	Maximum Residue / LOD (ppm)
Potato PDP Data (Import)	0.03796
Sweet Potato PDP Data (Domestic Plus Import)	0.07784
Sweet Potato Baby Food PDP Data (Domestic and Import)	0.0083

Table A.5.2. Commodity Specific Analysis for Aldicarb								
Commodity (Food)	Age Group			Source		Exposure %aPAD		
	Amount Consumed (g)			Anticipated Residue (ppm)		Using FTD or PDP Data		
	Infant (10 kg)	Pre-schooler (15 kg)	Females 13to49 (60 kg)	Monitoring (PDP)	Residue Threshold[1]	Infant	Pre-schooler	Adult-Female
Potato	71	142	142	0.0380	0.029	100	133	33
Sweet Potato	78	156	156	0.0778	0.026		300	75
Sweet Potato (bf)	78	156	156	0.0083	0.026	24		

bf = baby food
[1] Residue Threshold = aPAD / Consumption = 0.00027 mg/kg-bw/day / [Amount Consumed (kg/day) / Body Weight (kg)].
The residue threshold (i.e. residue level that would result in risk at the level of concern) presented in this table is based on preschoolers, the subgroup with highest exposure.